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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/931,700	08/16/2001	Frank Cuttitta	4239-63842	3744

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EXAMINER
UNGAR, SUSAN NMN

ART UNIT	PAPER NUMBER
1642	7

DATE MAILED: 01/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/931,700	Cuttitta et al
Examiner	**Art Unit**
Ungar	1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *one* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Nov 4, 2002* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-16* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1. Claims 1-16 are pending in the application and are currently under prosecution.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Anthony Caputa, Ph.D., Supervisory Patent Examiner at 703-308-3995. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

Groups A. Claims 1 and 15 are drawn to four peptides, each of which is a separate invention classified in Class 530, subclass 300+. Applicant is required to elect a single invention for examination.

Groups B. Claims 2 and 16 are drawn to an antibody reactive with at least one of four peptides, classified in Class 530, subclass 387.1. It is noted that by factorial analysis, claim 2 is drawn to 24 inventions. Applicant is required to elect a single invention for examination whereby the claimed antibody or combination of antibodies is specifically recited.

Groups C. Claims 3, 4 are drawn to a method of preventing or treating cancer comprising administering an amount of the peptides of claim 1, classified in Class 514, subclass 2+. It appears that this claim is drawn to a combination of peptides, therefore, the number of inventions is determined by

factorial analysis and claim 3 is drawn to 24 inventions. Applicant is required to elect a single invention for examination whereby the claimed peptide or combination of peptides is specifically recited.

Groups D. Claims 3, 4 are drawn to a method of preventing or treating cancer comprising administering an amount of the antibodies of claim 2, classified in Class 424, subclass 130. It appears that this claim is drawn to a combination of antibodies, therefore, the number of inventions is determined by factorial analysis and claim 3 is drawn to 24 inventions. Applicant is required to elect a single invention for examination whereby the claimed antibody or combination of antibodies is specifically recited.

Group E. Claims 5,6 are drawn to a method of diagnosing diseases by measuring the levels of adrenomedullin wherein the presence of adrenomedullin indicates the existence of a disease classified in Class 435, subclasses 4 and 7.1.

Group F. Claims 5,6 are drawn to a method of diagnosing diseases by measuring the levels of adrenomedullin wherein the absence of adrenomedullin indicates the existence of a disease classified in Class 435, subclasses 4 and 7.1.

Group G. Claims 5,6 are drawn to a method of monitoring diseases by measuring the levels of adrenomedullin wherein the presence of adrenomedullin indicates the existence of a disease classified in Class 435, subclasses 4 and 7.1.

Group H. Claims 5,6 are drawn to a method of monitoring diseases by measuring the levels of adrenomedullin wherein the absence of adrenomedullin indicates the existence of a disease classified in Class 435, subclasses 4 and 7.1.

Group I. Claims 5,6 are drawn to a method of diagnosing diseases by measuring the levels of adrenomedullin wherein the presence of adrenomedullin indicates the predisposition for a disease classified in Class 435, subclasses 4 and 7.1.

Group J. Claims 5,6 are drawn to a method of diagnosing diseases by measuring the levels of adrenomedullin wherein the absence of adrenomedullin indicates the predisposition for a disease classified in Class 435, subclasses 4 and 7.1.

Group K. Claims 5,6 are drawn to a method of monitoring diseases by measuring the levels of adrenomedullin wherein the presence of adrenomedullin indicates the predisposition for a disease classified in Class 435, subclasses 4 and 7.1.

Group L. Claims 5,6 are drawn to a method of monitoring diseases by measuring the levels of adrenomedullin wherein the absence of adrenomedullin indicates the predisposition for a disease classified in Class 435, subclasses 4 and 7.1.

Groups M. Claim 7 are drawn to a method of preventing or treating type II diabetes comprising administering an amount of the peptides of claim 1, classified in Class 514, subclass 2+. It appears that this claim is drawn to a

combination of peptides, therefore, the number of inventions is determined by factorial analysis and claim 7 is drawn to 24 inventions. Applicant is required to elect a single invention for examination whereby the claimed peptide or combination of peptides is specifically recited.

Groups N. Claim 7 are drawn to a method of preventing or treating type II diabetes comprising administering an amount of the antibodies of claim 2, classified in Class 424, subclass 130. It appears that this claim is drawn to a combination of antibodies, therefore, the number of inventions is determined by factorial analysis and claim 7 is drawn to 24 inventions. Applicant is required to elect a single invention for examination whereby the claimed antibody or combination of antibodies is specifically recited.

Group O. Claims 8, 9 are drawn to a method of diagnosing conditions related to pregnancy comprising administering an amount of the peptides of claim 1, classified in Class 514, subclass 2+. It appears that this claim is drawn to a combination of peptides, therefore, the number of inventions is determined by factorial analysis and claim 8 is drawn to 24 inventions. Applicant is required to elect a single invention for examination whereby the claimed peptide or combination of peptides is specifically recited.

Group P. Claims 8, 9 are drawn to a method of diagnosing conditions related to pregnancy comprising administering an amount of the antibodies of claim 2, classified in Class 424, subclass 130. It appears that this claim is drawn to a combination of antibodies, therefore, the number of inventions is determined by factorial analysis and claim 8 is drawn to 24 inventions.

Applicant is required to elect a single invention for examination whereby the claimed antibody or combination of antibodies is specifically recited.

Group Q. Claims 8, 9 are drawn to a method of treating conditions related to pregnancy comprising administering an amount of the peptides of claim 1, classified in Class 514, subclass 2+. It appears that this claim is drawn to a combination of peptides, therefore, the number of inventions is determined by factorial analysis and claim 8 is drawn to 24 inventions. Applicant is required to elect a single invention for examination whereby the claimed peptide or combination of peptides is specifically recited.

Group R. Claims 8, 9 are drawn to a method of treating conditions related to pregnancy comprising administering an amount of the antibodies of claim 2, classified in Class 424, subclass 130. It appears that this claim is drawn to a combination of antibodies, therefore, the number of inventions is determined by factorial analysis and claim 8 is drawn to 24 inventions. Applicant is required to elect a single invention for examination whereby the claimed antibody or combination of antibodies is specifically recited.

Group S. Claim 10 is drawn to a method of regulating activity in areas of CNS comprising administering an amount of the peptides of claim 1, classified in Class 514, subclass 2+. It appears that this claim is drawn to a combination of peptides, therefore, the number of inventions is determined by factorial analysis and claim 10 is drawn to 24 inventions. Applicant is required to elect a single invention for examination whereby the claimed peptide or combination of peptides is specifically recited.

Group T. Claim 10 is drawn a method of regulating activity in areas of CNS comprising administering an amount of the antibodies of claim 2, classified in Class 424, subclass 130. It appears that this claim is drawn to a combination of antibodies, therefore, the number of inventions is determined by factorial analysis and claim 10 is drawn to 24 inventions. Applicant is required to elect a single invention for examination whereby the claimed antibody or combination of antibodies is specifically recited.

Group U. Claim 11 is drawn to a method of regulating lessening the allergic response comprising administering an amount of the peptides of claim 1, classified in Class 514, subclass 2+. It appears that this claim is drawn to a combination of peptides, therefore, the number of inventions is determined by factorial analysis and claim 11 is drawn to 24 inventions. Applicant is required to elect a single invention for examination whereby the claimed peptide or combination of peptides is specifically recited.

Group V. Claim 11 is drawn a method of regulating lessening the allergic response comprising administering an amount of the antibodies of claim 2, classified in Class 424, subclass 130.1. It appears that this claim is drawn to a combination of antibodies, therefore, the number of inventions is determined by factorial analysis and claim 11 is drawn to 24 inventions. Applicant is required to elect a single invention for examination whereby the claimed antibody or combination of antibodies is specifically recited.

Group W. Claim 11 is drawn to a method of inhibiting the allergic response comprising administering an amount of the peptides of claim 1,

classified in Class 514, subclass 2+. It appears that this claim is drawn to a combination of peptides, therefore, the number of inventions is determined by factorial analysis and claim 11 is drawn to 24 inventions. Applicant is required to elect a single invention for examination whereby the claimed peptide or combination of peptides is specifically recited.

Group X. Claim 11 is drawn a method of inhibiting the allergic response comprising administering an amount of the antibodies of claim 2, classified in Class 424, subclass 130. It appears that this claim is drawn to a combination of antibodies, therefore, the number of inventions is determined by factorial analysis and claim 11 is drawn to 24 inventions. Applicant is required to elect a single invention for examination whereby the claimed antibody or combination of antibodies is specifically recited.

Group Y. Claim 12 is drawn to a method of treating/inhibiting bacterial infections comprising administering an amount of the peptides of claim 1, classified in Class 514, subclass 2+. It appears that this claim is drawn to a combination of peptides, therefore, the number of inventions is determined by factorial analysis and claim 12 is drawn to 24 inventions. Applicant is required to elect a single invention for examination whereby the claimed peptide or combination of peptides is specifically recited.

Group Z. Claim 12 is drawn to a method of treating/ inhibiting bacterial infections comprising administering an amount of the antibodies of claim 2, classified in Class 424, subclass 130. It appears that this claim is drawn to a combination of antibodies, therefore, the number of inventions is determined

by factorial analysis and claim 12 is drawn to 24 inventions. Applicant is required to elect a single invention for examination whereby the claimed antibody or combination of antibodies is specifically recited.

Group AA. Claim 12 is drawn to is drawn to a method of treating/ preventing bacterial infections comprising administering an amount of the peptides of claim 1, classified in Class 514, subclass 2+. It appears that this claim is drawn to a combination of peptides, therefore, the number of inventions is determined by factorial analysis and claim 12 is drawn to 24 inventions. Applicant is required to elect a single invention for examination whereby the claimed peptide or combination of peptides is specifically recited.

Group AB. Claim 12 is drawn a method of a method of treating/ preventing bacterial infections comprising administering an amount of the antibodies of claim 2, classified in Class 424, subclass 130. It appears that this claim is drawn to a combination of antibodies, therefore, the number of inventions is determined by factorial analysis and claim 12 is drawn to 24 inventions. Applicant is required to elect a single invention for examination whereby the claimed antibody or combination of antibodies is specifically recited.

Group AC. Claim 12 is drawn to a method of treating/inhibiting fungal infections comprising administering an amount of the peptides of claim 1, classified in Class 514, subclass 2+. It appears that this claim is drawn to a combination of peptides, therefore, the number of inventions is determined by factorial analysis and claim 12 is drawn to 24 inventions. Applicant is required

to elect a single invention for examination whereby the claimed peptide or combination of peptides is specifically recited.

Group AD. Claim 12 is drawn a method of is drawn to a method of treating/ inhibiting fungal infections comprising administering an amount of the antibodies of claim 2, classified in Class 424, subclass 130. It appears that this claim is drawn to a combination of antibodies, therefore, the number of inventions is determined by factorial analysis and claim 12 is drawn to 24 inventions. Applicant is required to elect a single invention for examination whereby the claimed antibody or combination of antibodies is specifically recited.

Group AE. Claim 12 is drawn to is drawn to a method of treating/ preventing fungal infections comprising administering an amount of the peptides of claim 1, classified in Class 514, subclass 2+. It appears that this claim is drawn to a combination of peptides, therefore, the number of inventions is determined by factorial analysis and claim 12 is drawn to 24 inventions. Applicant is required to elect a single invention for examination whereby the claimed peptide or combination of peptides is specifically recited.

Group AF. Claim 12 is drawn a method of a method of treating/ preventing fungal infections comprising administering an amount of the antibodies of claim 2, classified in Class 514, subclass 2+. It appears that this claim is drawn to a combination of antibodies, therefore, the number of inventions is determined by factorial analysis and claim 12 is drawn to 24 inventions.

Applicant is required to elect a single invention for examination whereby the claimed antibody or combination of antibodies is specifically recited.

Group AG. Claim 13 is drawn to is drawn to a method of facilitating healing of chaffed skin comprising administering an amount of the peptides of claim 1, classified in Class 514, subclass 2+. It appears that this claim is drawn to a combination of peptides, therefore, the number of inventions is determined by factorial analysis and claim 13 is drawn to 24 inventions. Applicant is required to elect a single invention for examination whereby the claimed peptide or combination of peptides is specifically recited.

Group AH. Claim 13 is drawn to is drawn to a method of facilitating healing of skin lesions comprising administering an amount of the peptides of claim 1, classified in Class 514, subclass 2+. It appears that this claim is drawn to a combination of peptides, therefore, the number of inventions is determined by factorial analysis and claim 13 is drawn to 24 inventions. Applicant is required to elect a single invention for examination whereby the claimed peptide or combination of peptides is specifically recited.

Group AI. Claim 13 is drawn to is drawn to a method of facilitating healing of wound repair comprising administering an amount of the peptides of claim 1, classified in Class 514, subclass 2+. It appears that this claim is drawn to a combination of peptides, therefore, the number of inventions is determined by factorial analysis and claim 13 is drawn to 24 inventions. Applicant is required to elect a single invention for examination whereby the claimed peptide or combination of peptides is specifically recited.

Group AJ. Claim 13 is drawn to is drawn to a method of facilitating healing of surgical incisions comprising administering an amount of the peptides of claim 1, classified in Class 514, subclass 2+. It appears that this claim is drawn to a combination of peptides, therefore, the number of inventions is determined by factorial analysis and claim 13 is drawn to 24 inventions. Applicant is required to elect a single invention for examination whereby the claimed peptide or combination of peptides is specifically recited.

Group AK. Claim 14 is drawn to a method of promoting organ and bone development comprising administering an amount of the peptides of claim 1, classified in Class 514, subclass 2+. It appears that this claim is drawn to a combination of peptides, therefore, the number of inventions is determined by factorial analysis and claim 14 is drawn to 24 inventions. Applicant is required to elect a single invention for examination whereby the claimed peptide or combination of peptides is specifically recited.

Group AL. Claim 14 is drawn a method of is drawn to a method of promoting organ and bone development comprising administering an amount of the antibodies of claim 2, classified in Class 514, subclass 2+. It appears that this claim is drawn to a combination of peptides, therefore, the number of inventions is determined by factorial analysis and claim 14 is drawn to 24 inventions. Applicant is required to elect a single invention for examination whereby the claimed peptide or combination of peptides is specifically recited.

measuring the levels of adrenomedullin wherein the presence of adrenomedullin indicates the existence of a disease classified in Class 435, subclasses 4 and 7.1.

3. The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups A and B as disclosed are biologically and chemically distinct, unrelated in structure and function, made by and used in different methods and are therefore distinct inventions.

The inventions of Groups C-AL are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

The inventions of Groups A and C, M, O, Q, S, U, W, Y, AA, AC, AE, AG-AL are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the peptide product as claimed can be used in a materially different process such as an antigen for the production of antibodies.

The inventions of Groups B and D, N, P, R, T, V, X, Z, AB, AD, AF are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the antibody product as claimed can be used

in a materially different process such as an antigen for the production of anti-idiotypic antibodies.

The inventions of Groups A/B and E-L are not at all related because the products of Groups A/B are not used in any of the methods of Groups A/B.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

7. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar
Primary Patent Examiner
January 10, 2003